K111425

APR 20 2012

510(k) SUMMARY

OLYMPUS LTF-S190-10
OLYMPUS OTV-S190
OLYMPUS CLV-S190
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE
VISERA ELITE VIDEO SYSTEM CENTER
VISERA ELITE XENON LIGHT SOURCE

April 09, 2012

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No: 8010047

- Official Correspondent:

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Regulatory Affairs & Quality Assurance
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- Manufacturer:

(LTF-S190-10)
Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No.: 9610595

(OTV-S190, CLV-S190)
SHIRAKAWA OLYMPUS CO., LTD.
3-1,
Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name:

OLYMPUS LTF-S190-10
OLYMPUS OTV-S190
OLYMPUS CLV-S190

- Common Name:

ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE
VISERA ELITE VIDEO SYSTEM CENTER
VISERA ELITE XENON LIGHT SOURCE

: 00600

- Regulation Number: 21 CFR 884.1720
  21 CFR 876.1500
  21 CFR 874.4680
- Regulation Name: Gynecologic laparoscope and accessories
  Endoscope and Accessories
  Bronchoscope (flexible or rigid) and accessories
- Regulatory Class: II
- Classification Panel: General and plastic surgery,
  Obstetrics/Gynecology
  Ear Nose & Throat
- Product Code: HET, GCJ, FGB, EOQ, EOB and NWB

3 Predicate Device Information

Subject Device (Part of this submission)	Predicate Device	PD's 510(k) No.	Manufacturer
OLYMPUS LTF-S190-10 LAPRO-THORACO VIDEOSCOPE	HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF Type VH	K080948	Aizu Olympus Co., Ltd. 500 Aza-Muranishi, Ooaza-lidera, Monden-cho, Aizuwakamatsu-shi, Fukushima, Japan 965-8520 Establishment Registration No.: 9610595
OLYMPUS CLV-S190 VISERA ELITE XENON LIGHT SOURCE	EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180	K061313 K062049	SHIRAKAWA OLYMPUS CO., LTD. 3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima, Japan 961-8061 Establishment Registration No: 3002808148
OLYMPUS OTV-S190 VISERA ELITE VIDEO SYSTEM CENTER	EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CV-180	K061313 K062049 K100584	

4 Device Description

ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10 is a flexible video endoscope used for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs which is basically identical to predicate device LTF-VH, for the same application area.

The subject device LTF-S190-10 is utilized with the OLYMPUS OTV-S190 VISERA ELITE VIDEO SYSTEM CENTER and OLYMPUS CLV-S190 VISERA ELITE XENON LIGHT SOURCE. The subject endoscope LTF-S190-10 connects to the VISERA ELITE XENON LIGHT SOURCE OLYMPUS CLV-S190 through the light guide connector and the video plugs into video system processors, OTV-S190.

The compatible VISERA ELITE VIDEO SYSTEM CENTER OLYMPUS OTV-S190 and VISERA ELITE XENON LIGHT SOURCE OLYMPUS CLV-S190 are intended for endoscopic diagnosis, treatment and video observation.

The OTV-S190 contains the video signal processing technology which enables the endoscope to illuminate, enhance, view, record and transmit video data of endoscopic images. The OLYMPUS OTV-S190 allows image display on HDTV (16:9).

In addition, both the OTV-S190 and CLV-S190 can be used with any specified Olympus flexible and rigid endoscope models, including rhino-laryngoscopes, tracheal intubation scopes, transnasal esophago scopes, hysteroscopes, cystoscopes, ureterorenoscopes, laparo-thoracoscopes.

5 Indications for Use

- OLYMPUS LTF-S190-10 ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE

This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

This instrument must not to be used for observation or treatment of the heart and must not contact the heart or any area near the heart. In addition, this instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.

- OLYMPUS OTV-S190 VISERA ELITE VIDEO SYSTEM CENTER

This video system center has been designed to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

- OLYMPUS CLV-S190 VISERA ELITE XENON LIGHT SOURCE

This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

6 Comparison of Technological Characteristics

The OLYMPUS LTF-S190-10, OLYMPUS OTV-S190, OLYMPUS CLV-S190 are basically identical to the predicate device in intended use, and similar in specifications.

The subject LTF-S190-10 is nearly identical to the predicate LTF-VH device. It has identical spefications to the predicate device except for; (1) a wider field of view, (2) an additional reprocessing method (steam sterilization) and (3) incorpotion of a Fog Free Function.

Compared to the predicate device, the OTV-S190 incorporates the following features: (1) Provide an improved high quality endoscopic image and (2) incoropration of a Fog Free Function.

The improved endoscopic imaging during procedures is achieved by the following modifications; A) noise reduction, B) pre-freeze image capture and C) a brighter and more contrasted NBI observation.

The subject CLV-S190 has almost the same in design and function to its predicate CLV-180, and except as following features:
(1) Built-in type power fuse is incorporated
(2) Provides high-definition images when connected to the OTV-S190 and the LTF-S190-10
and
(3) Allow for a brighter NBI image
(4) The subject device does not have an air feeding pump.

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

As a new patient contacting material was used, the following biocompatibility tests were performed on the subject endoscope in accordance with "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, Blue Book Memo, G95-13"

- Cytotoxicity test
- Sensiization test
- Intracutaneous Reaction test

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

The following bench tests were conducted to demonstrate the substaintal equivalence and safety and effectiveness of the subject devices:

- Mechanical durability testing
- Electrical safety testing
- Electromagnetic compatibility testing
- Thermal safety testing
- Effectiveness / performance testing of Fog Free Function
- Image quality improvement / spectrum testing for multiple CCD
- Phototoxicity analysis testing

The following standards have been applied to the subject VISERA ELITE SYSTEM :

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971
- ASTM E1837-96 (Reapproved 2007)
- ANSI/AAMI/ISO 11135-1
- ISO 10993-1
- ISO 10993-5
- ISO 10993-7
- ISO 10993-10
- Light and Near-Infrared Radiation: TLV Physical Agents
- Ultraviolet Radiation: TLV Physical Agents

8 Conclusion

When compared to the predicate device, the OLYMPUS LTF-S190-10, OLYMPUS OTV-S190 and OLYMPUS CLV-S190 do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device and therefore is Substantially Equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OLYMPUS MEDICAL SYSTEM CORP.
% Ms. Sheri Musgnung
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway P.O. Box 610
CENTER VALLEY PA 18034

APR 20 2012

Re: K111425
Trade/Device Name: ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE, VISERA ELITE VIDEO SYSTEM CENTER and VISERA ELITE XENON LIGHT SOURCE
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET, GCJ, FGB, EOQ, EOB and NWB
Dated: April 9, 2012
Received: April 17, 2012

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111425

Device Name: ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE

Indications For Use:

This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

This instrument must not to be used for observation or treatment of the heart and must not contact the heart or any area near the heart. In addition, this instrument must not come into contact with any device or therapeutic accessory that contacts the heart or any area near the heart.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111425

Indications for Use

510(k) Number (if known): K111425

Device Name: VISERA ELITE VIDEO SYSTEM CENTER

Indications For Use:

This video system center has been designed to be used with OLYMPUS camera heads, endoscopes, light sources, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111425

Indications for Use

510(k) Number (if known): K111425

Device Name: VISERA ELITE XENON LIGHT SOURCE

Indications For Use:

This light source has been designed to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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